Policy and Procedure	
Title:	**Impact Assessment of Investigational/Humanitarian Devices - Research**
Maintained by:	Baylor St. Luke's Medical Center Research Office
Reviewed by:	Patient Financial Services Supply Chain
Approved by:	Sr. Vice President and Chief Operating Officer
Effective date:	January 2022
Next review date:	January 2025

REVISION SUMMARY

Date	Referenced Section(s)	Change
November 2017	Whole Document	New

SCOPE

Applicable to: CHI St. Luke's Health–Baylor St. Luke's Medical Center (BSLMC)
Department(s): All groups involved in research activities at BSLMC.

DEFINITION(S)

Humanitarian Device Exemption (HDE): An HDE application is submitted to the FDA to obtain approval for a HUD to be administered at an institution. The HDE must contain sufficient information for FDA to determine that the probable benefit to health outweighs the risk of injury or illness, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Once the HDE is approved, an Institutional Review Board must review and approve use of the HUD.

Humanitarian Use Device (HUD): An HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year. The Office of Orphan Products Development (OOPD) determines if a device meets specific requirements, including scientific rationale and population prevalence, for designation as a HUD.

Investigational Device Exemption (IDE): An investigational device exemption is issued by the FDA and allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data. An IDE may be held by a commercial sponsor or an investigator.

POLICY

All device studies that require the hospital to purchase the device must undergo a financial impact analysis. This process provides for responsible allocation of hospital resources.

PROCEDURES

A. Impact assessment initiation

a. For all investigational/humanitarian use devices studies to be conducted at the hospital, study teams must submit the BSLMC IDE & HDE Request Form and required documents to initiate the impact assessment process.
   i. Financial impact assessment process should be initiated as early in the study startup process as possible, as findings may impact study budgets.
   ii. Financial impact assessment must be completed before BSLMC Administrative Approval can be given. See policy and procedure - *Protocol Administrative Review - Research*

B. Device impact assessment

a. BSLMC Supply Chain will confirm the study device pricing and compare pricing to similar devices in use at the hospital, if applicable.

   i. For studies where the sponsor provides the device free of charge, Supply Chain will set up the purchase order and notify BSLMC Research Office of setup. This concludes the impact assessment for the study. BSLMC Research Office will then proceed with administrative review.

   ii. For studies where the sponsor does not provide the device free of charge, Supply Chain will forward the pricing information and study documentation to BSLMC Finance.
      1. Finance will complete a financial impact assessment of the study.

C. Executive leadership review of impact assessment

a. Upon completion of the financial impact assessment, Finance will forward the analysis to the BSLMC Executive responsible for device study review.

D. Notification of study team

a. BSLMC Research Office will notify the study team of outcome.
   i. If the impact assessment was approved, study team shall proceed with budget negotiations with the sponsor.
   ii. If the impact assessment was not approved, BSLMC Research Office will provide the study team with a summary of revisions required for approval, as applicable. The study team may address these items and resubmit to BSLMC Research office.

E. Routing of device purchase agreement

a. For approved device studies, BSLMC Research Office will request the IRB approval letter from study team.

b. After receiving the IRB approval letter, BSLMC Research Office will forward approval letter, device form, financial impact assessment with Executive determination, and device purchase agreement to Supply Chain.

c. Supply Chain will execute the device purchase agreement on behalf of BSLMC and return a copy to the BSLMC Research Office.

d. BSLMC Research Office will forward the fully executed purchase agreement to the study team for study records and proceed with administrative approval.

F. Guide to Conducting Clinical Research at BSLMC

a. Study teams should refer to the Guide for specific details on the procedures described in this policy.

CROSS-REFERENCE(S)
Policy and Procedure, *Protocol Administrative Review – Research*

RELATED DOCUMENTS
- Guide to Conducting Clinical Research at BSLMC
- BSLMC Administrative Application
- BSLMC Investigational Device Exemption and Humanitarian Device Exemption Request Form
- BSLMC Process for Device Study Impact Analysis flowchart